

JAN 24 2003



**Business Group  
Diagnostics**

Bayer Corporation  
511 Benedict Avenue  
Tarrytown, NY 10591-5097  
Phone: 914 631-8000  
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<http://www.bayerdiag.com>

**Summary of Safety and Effectiveness**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number is: K030102

**1. Submitter's Name and Address**

Bayer HealthCare LLC  
Diagnostics Division  
511 Benedict Avenue  
Tarrytown, NY 10591

Contact Person: Kenneth T. Edds, Ph.D.  
Telephone: 914-524-2446  
Fax: 914-524-2500  
e-mail: [ken.edds.b@bayer.com](mailto:ken.edds.b@bayer.com)

Establishment Registration Number: 2432235

- |                               |   |
|-------------------------------|---|
| <b>2. Device Name:</b>        | Liquid Cardiac Markers 1,2,3            |
| <b>Proprietary/Trade Name</b> | Bayer Liquid Cardiac Markers 1,2,3      |
| <b>Common Name:</b>           | Quality Control Material                |
| <b>Classification Name:</b>   | Enzyme Controls (assayed and unassayed) |
| <b>Classification:</b>        | Class I                                 |
| <b>Regulation Number:</b>     | 21 CFR 862.1660                         |
| <b>Panel:</b>                 | Chemistry (75)                          |
| <b>Product Code:</b>          | JJT                                     |

**3. Predicate Device:**

Liquid Cardiac Markers 1,2,3  
Premarket Notification Number: K960246

**4. Device Description:**

The Bayer Liquid Cardiac Markers 1, 2, 3 are three separate levels of quality control material prepared from human serum with recombinant human CK-MB, human proteins, Digitoxin, Myoglobin, Troponin-I and Homocysteine.

**5. Intended Use:**

The Bayer Liquid Cardiac Markers 1, 2, and 3 are assayed control materials for in vitro diagnostic use to monitor the precision and accuracy of immunochemical mass measurement test procedures for the ADVIA Centaur® and ACS:180® Systems.

**6. Substantial Equivalence:**

The Bayer Liquid Cardiac Markers 1, 2, and 3 are identical in intended use and fundamental scientific technology as the previously cleared Liquid Cardiac Markers 1,2, 3. The only difference in these controls is the addition of one new analyte, Homocysteine.

As with the predicate device, the control material is liquid and requires no further treatment before use. These controls are only for use on the Bayer ADVIA Centaur® and ACS:180® Systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN 24 2003

Kenneth T. Edds, Ph.D.  
Manager, Regulatory Affairs  
Bayer Corporation  
Bayer HealthCare LLC  
511 Benedict Avenue  
Tarrytown, NY 10591

Re: k030102  
Trade/Device Name: Bayer Liquid Cardiac Makers 1, 2, 3  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality Control Material (Assayed and Unassayed)  
Regulatory Class: Class I  
Product Code: JJT  
Dated: January 10, 2003  
Received: January 10, 2003

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

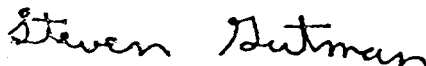
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K030102

Device Name: Bayer Liquid Cardiac Markers 1, 2, 3

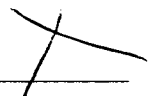
**Indications for Use:**

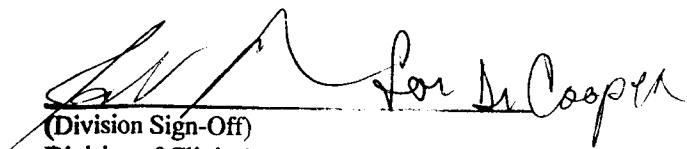
The Bayer Liquid Cardiac Markers 1, 2, 3 are assayed control materials for in vitro diagnostic use to monitor the precision and accuracy of immunochemical mass measurement test procedures for the ADVIA Centaur® and ACS:180® Systems.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE, IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109) (Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical

510(k) Number K030102